

B. PACKAGE LEAFLET FOR RADIOPHARMACEUTICALS

Package leaflet: Information for the patient

Galliad 0.74 -1.85 GBq radionuclide generator / gineadóir radanúiclíde

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Galliad is and what it is used for.
2. What you need to know before the Gallium (^{68}Ga) chloride solution obtained with Galliad is used
3. How Gallium (^{68}Ga) chloride solution obtained with Galliad is used
4. Possible side effects
5. How Galliad is stored
6. Contents of the pack and other information

1. What Galliad is and what it is used for

This medicine is a radiopharmaceutical product not intended for direct use in patient.

Galliad is a germanium (^{68}Ge) / gallium (^{68}Ga) radionuclide generator, a device used to obtain a solution of gallium (^{68}Ga) chloride.

The obtained gallium (^{68}Ga) chloride solution is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound, here ^{68}Ga .

Galliad is used to label certain medicines that have been specially developed and approved for the use with the active substance gallium (^{68}Ga) chloride. These medicines act as carriers to take the radioactive ^{68}Ga to where it is needed. These may be substances that have been designed to recognise a particular type of cell in the body, including tumour cells (cancer). The low amount of radioactivity administered can be detected outside of the body by special cameras.

Please refer to the package leaflet of the medicine that is to be radiolabelled with gallium (^{68}Ga) chloride. The nuclear medicine doctor will explain to you what type of examination will be performed with this product.

The use of a ^{68}Ga -labelled medicinal product does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical overcomes the risk due to radiation.

2. What you need to know before the Gallium (^{68}Ga) chloride solution obtained with Galliad is used

The Gallium (^{68}Ga) chloride solution obtained with Galliad must not be used

- if you are allergic to gallium (^{68}Ga) chloride or any of the other ingredients of this medicine (listed in section 6).

If you are using a ^{68}Ga -labelled medicinal product, you should read information on contraindications in the package leaflet of the product to be radiolabelled.

Warnings and precautions

For information concerning special warnings and special precautions for use of ^{68}Ga labelled medicinal products please refer to the Package Leaflet of the medicinal product to be radiolabelled.

Children and adolescents

Please speak to your nuclear medicine doctor if you or your child are under 18 years old

Other medicines and Gallium (^{68}Ga) chloride solution

Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images.

It is not known whether gallium (^{68}Ga) chloride may interact with other medicines as specified studies have not been carried out.

For information concerning interactions associated with the use of ^{68}Ga labelled medicinal products refer to the Package Leaflet of the medicinal product to be radiolabelled.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given medicines radiolabelled with Galliad.

You must inform the nuclear medicine doctor before the administration of medicines radiolabelled with Galliad if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

If you are pregnant

The nuclear medicine doctor will only administer this product during pregnancy if a benefit is expected which would outweigh the risks.

If you are breast-feeding

You will be asked to stop breast-feeding. Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines

There could be effects on your ability to drive and to use machines due to the medicine used in combination with Galliad. Please read the package leaflet of that medicine carefully.

3. How Gallium (^{68}Ga) chloride solution obtained with Galliad is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Galliad will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of medicine radiolabelled with Galliad to be used in your case. It will be the smallest quantity necessary to achieve the appropriate outcome, depending on the medicine to be labelled and its intended use. Please read the package leaflet of the medicine that is to be radiolabelled for more information.

Administration of Gallium (^{68}Ga) chloride solution obtained with Galliad and conduct of the procedure

You will not get the Gallium (^{68}Ga) chloride solution, but another product radiolabelled with Galliad. Gallium (^{68}Ga) chloride solution must be used only in combination with another medicine which has been specifically developed for being combined (radiolabelled) with Galliad. You will only be given the final

radiolabelled product.

Duration of the procedure

Your nuclear medicine doctor will inform you about the usual duration of the procedure after the administration of the medicine radiolabelled with Galliad.

After administration of the medicine radiolabelled with Galliad has been performed

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving the medicine radiolabelled with Galliad. Contact your nuclear medicine doctor if you have any questions.

If you have been given more medicine radiolabelled with Galliad than you should

An overdose is unlikely, because you will only receive the medicine radiolabelled with Galliad precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment.

Should you have any further question on the use of this product, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, the medicine radiolabelled with Galliad can cause side effects, although not everybody gets them.

After the medicine radiolabelled with Galliad is administered, it will deliver low amounts of ionising radiation with the least risk of cancer and hereditary abnormalities.

Reporting of side effects

If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in the leaflet.. You can also report side effects directly via

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How Galliad is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only:

The radionuclide generator must not be used after the expiry date stated on the container after "EXP".

Do not dismantle the plastic case. Do not store above 25°C.

The gallium (^{68}Ga) chloride solution obtained with Galliad must be used immediately.

6. Contents of the pack and other information

What Galliad contains

The active substances is Gallium (^{68}Ga) chloride solution

The other ingredients are: Titanium dioxide (matrix)

Sterile 0.1 N hydrochloric acid (solution for elution)

What Galliad looks like and contents of the pack

You will not need to obtain or handle this medicine.

Marketing Authorisation Holder and Manufacturer

IRE-Elit

Avenue de l'Espérance

B-6220 Fleurus

Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

Country	Product name
Austria	Galli Ad 0.74 – 1.85 GBq, Radionuklidgenerator
Belgium	Galli Ad 0.74 – 1.85 GBq, radionuclidegenerator / générateur radiopharmaceutique / Radionuklidgenerator/
Bulgaria	Galli Ad 0.74 – 1.85 GBq, Радионуклиден генератор
Czechia	Galliad
Croatia	Galliad 0,74 – 1,85 GBq generator radionuklida
Cyprus	Galli Ad 0.74 – 1.85 GBq, Γεννήτρια ραδιονουκλιδίου
Denmark	Galli Ad 0.74 – 1.85 GBq, radionuklidgenerator
Estonia	Galliad
Finland	Galliad 0.74 – 1.85 GBq, radionuklidgeneraattori / radionuklidgenerator
France	Galliad 0.74 – 1.85 GBq, générateur radiopharmaceutique
Germany	GalliAd 0.74 – 1.85 GBq, Radionuklidgenerator
Greece	Galli Ad 0.74 – 1.85 GBq, Γεννήτρια ραδιονουκλιδίου
Hungary	Galli Ad 0.74 – 1.85 GBq, radioaktív izotóp generátor
Ireland	Galliad 0.74 - 1.85 GBq, radionuclide generator
Italy	Germanio cloruro (^{68}Ge)/Gallio cloruro (^{68}Ga) IRE-ELiT
Latvia	Galliad 0,74 – 1,85 GBq radionuklīdu ģeneratori
Lithuania	Galliad 0,74 – 1,85 GBq radionuklidų generatorius
Luxemburg	Galli Ad 0.74 – 1.85 GBq, générateur radiopharmaceutique
Malta	Galli Ad 0.74 – 1.85 GBq, radionuclide generator / generatur radjunuklidu
Netherlands	GalliAd 0,74 – 1,85 GBq, radionuclidegenerator
Norway	Galliad
Poland	Galliad
Portugal	Galli Ad 0.74 – 1.85 GBq, gerador de radionuclidos
Romania	Galli Ad 0.74 – 1.85 GBq, generator de radionuclizi
Slovakia	Galli Ad 0.74 – 1.85 GBq, rádionuklidový generátor
Slovenia	Galliad 0,74 – 1,85 GBq radionuklidni generator
Spain	Galli Ad 0.74 – 1.85 GBq, generador de radionuclido
Sweden	Galliad 0.74 – 1.85 GBq, radionuklidgenerator
United Kingdom	GalliAd 0.74 – 1.85 GBq, radionuclide generator

This leaflet was last revised on

The following information is intended for medical or healthcare professionals only:

The complete SmPC of Galliad 0.74 – 1.85 GBq, radionuclide generator is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.